

Attachment 4- Revised Summary Information BK120008

III. SUMMARY INFORMATION

510(k) Summary

(New, Separate Submission to Cleared BK060006)

Submitter:	Cascade Medical Enterprises, LLC 20 Greenup Court Wayne, New Jersey 07470 Phone: (973) 956-7607 Fax: 973-836-0216
Contact Person:	Nicholas Grippi
Device Trade Name:	Cascade Medical FIBRINET® System
Common Name:	Platelet and Plasma Separator for Bone Graft Handling
Classification Name:	Automated Blood Cell Separator, Code: ORG 21 CFR 864.9245
Substantial Equivalence:	The device in this submission is identical to the device cleared in clearance BK020051 and this submission is for administrative purposes only. See MTF Authorization Letter (Attachment 2) for proof of Substantial Equivalence.
Device Description:	The Cascade Medical FIBRINET® System is a self-contained disposable kit. Each kit consists of two or more sterile evacuated blood collection tubes, needles and a transfer device. (No Change from BK060006)
Intended Use:	The Cascade Medical FIBRINET® System is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
Technological Aspects:	Identical to the currently marketed product cleared in BK060006.